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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/466,935 12/20/99 LIVSHITS V 0010-1070-0

HM12/1102
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EXAMINER

STEADMAN, D

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

11/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.		Applicant(s)	
	09/466,935		LIVSHITS ET AL.	
	Examiner		Art Unit	
	David J. Steadman		1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 and 17 is/are allowed.
- 6) ☒ Claim(s) 11-15 and 18-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
- 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
- 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2, 3</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Claims 11-21 are pending in the application.

Receipt of IDS reference AV, English-language translation of priority document RU 98123511, cancellation of claims 1-10, and addition of claims 11-21 in Paper No. 9 is acknowledged.

Applicants' arguments in Paper No. 9, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

1. Rejection of claims 11-15 under 35 U.S.C. 112, second paragraph, is maintained. The term "increased" in claims 11 (claims 18-21 dependent therefrom) and 12-15 is unclear absent a statement defining to what the level of resistance or protein activity is being compared. The term "increased" is a relative term and the claim should define and clearly state as to what the resistance or protein activity is being compared (i.e., resistance or protein activity in comparison to what level of resistance or protein activity?) by, for example, inserting "in comparison to a wild-type Escherichia bacterium" following "increased".

Applicants argue that the claims have been amended to obviate 35 U.S.C. 112, second paragraph rejections. However, applicants have replaced the relative term “enhanced” with the relative term “increased”. Therefore, the rejection is maintained.

2. Claims 14 and 15 are confusing in the recitation of the term “DNA coding for the protein” as it is unclear as to whether “the protein” refers to a protein comprising the amino acid sequence of SEQ ID NO:4 or a protein comprising the amino acid sequence of SEQ ID NO:2. It is suggested that applicants clarify the meaning of the claims.

3. Rejection of claims 11, 12, and 18-21 under 35 U.S.C. 112, first paragraph, is maintained. The rejection was fully explained in a previous Office action. Applicants argue that due to amendment to the claims, the rejection of the claims under 35 U.S.C. 112, first paragraph is obviated. This argument is not found persuasive as the amendment to the claims has not fully described the claimed bacterium for the reasons stated below.

As stated in the previous Office action, claims 11 (claims 18-21 dependent therefrom) are directed to a genus of bacteria with increased activity of the polypeptide of SEQ ID NO:4 or increased activities of the polypeptides of SEQ ID NOs:2 and 4. The specification teaches only two representative species of such bacteria, i.e., bacteria transformed with the polynucleotide of SEQ ID NO:3 or bacteria transformed with the polynucleotides of SEQ ID NOs:1 and 3. The specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being bacteria with an increased activity of the polypeptide of SEQ ID NO:4 or increased activities of the polypeptides of SEQ ID NOs:2 and 4. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise,

and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

4. Rejection of claims 11, 12, and 18-21 under 35 U.S.C. 112, first paragraph, is maintained. The rejection was fully explained in a previous Office action. Applicants argue that due to amendment to the claims, the enablement rejection of the claims under 35 U.S.C. 112, first paragraph is obviated. This argument is not found persuasive as the amendment to the claims has not fully enabled the claimed bacterium for the reasons stated below.

The specification, while being enabling for a bacterium transformed with the polynucleotide of SEQ ID NO:3 encoding SEQ ID NO:4 or a bacterium transformed with polynucleotides of SEQ ID NOs:1 and 3 encoding the polypeptides of SEQ ID NOs:2 and 4, respectively, does not reasonably provide enablement for **any** bacterium with increased activity of the polypeptide of SEQ ID NO:4 or increased activities of the polypeptides of SEQ ID NOs:2 and 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 11 (claims 18-21 dependent therefrom) and 12 are so broad as to encompass **any** bacterium with increased activity of the polypeptide of SEQ ID NO:4 or increased activities of the polypeptides of SEQ ID NOs:2 and 4. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of bacteria broadly encompassed by the claims. In this case the disclosure is limited to a bacterium transformed with the polynucleotide of SEQ ID NO:3 encoding SEQ ID NO:4 or a bacterium

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transformed with polynucleotides of SEQ ID NOs:1 and 3 encoding the polypeptides of SEQ ID NOs:2 and 4.

While techniques of enhancing enzymatic activity in a host cell are known in the art, it is not routine to screen for bacteria with increased activity of a polypeptide, as encompassed by the instant claims. Furthermore, a reasonable expectation of success in obtaining bacteria with the desired polypeptide activity is highly unpredictable.

The specification does not support the broad scope of the claims which encompass **any** bacterium with increased activity of the polypeptide of SEQ ID NO:4 or increased activities of the polypeptides of SEQ ID NOs:2 and 4 because the specification does not establish: (A) methods of screening and/or isolating **any** bacterium with increased activity of the polypeptide of SEQ ID NO:4 or increased activities of the polypeptides of SEQ ID NOs:2 and 4; (B) methods for increasing the activity of the polypeptide of SEQ ID NO:4 or the polypeptides of SEQ ID NOs:2 and 4 other than by transforming a bacterium with nucleic acids expressing said proteins; (C) the general tolerance of the methods and extent of such tolerance; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications of **any** bacterium with increased activity of the polypeptide of SEQ ID NO:4 or increased activities of the polypeptides of SEQ ID NOs:2 and 4. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance,

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determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Conclusion

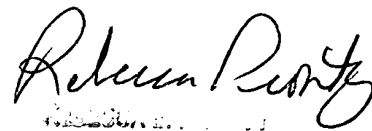
5. Claims 16 and 17 are in condition for allowance.
6. Claims 11-15 and 18-21 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Applicants' addition of claims 14 and 15 necessitated the new ground(s) of rejection presented in this office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The examiner can normally be reached Monday-Friday from 8:00 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Art Unit is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.



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